

ABSTRACT

The present invention relates to modifying rapid immunochromatographic ("ICT") tests for the detection of characteristic carbohydrate antigens of bacteria that are known to be causative of otitis media and respiratory diseases in children under the age of approximately 12 years. Children of this age group are also prone to nasopharyngeal colonization with the same bacteria, and urine samples taken from colonized, but otherwise healthy, children were shown to exhibit an unduly high incidence of test results that were false positive for the presence of disease.

The test modifications, which maintain the test sensitivity unchanged and the test specificity at a value above 90% were developed to insure that healthy, albeit colonized, children were not medicated for disease the bacteria are known to cause. The modifications involve either (1) reducing the total amount of antibodies to the carbohydrate antigen employed in each test, (2) adding at least one fixed "scrub" line located just prior to the capture line in the sample flow path to the preprepared ICT test strip to "scrub" out an identical amount of target antigen from all bodily fluid test samples obtained from both colonized but otherwise healthy children and diseased children, or (3) combinations of (1) and (2).